II. REMARKS

Preliminary Remarks:

The specification is amended to correct and update the information about related applications in the first paragraph, and to add SEQ ID NOs to the text pursuant to 35 C.F.R. § 1.821(d).

Claims 1 and 6-15 are canceled without prejudice as being directed to a non-elected invention, and claim 4 is canceled as being redundant of amended claim 2. Claims 2, 3, and 5 are amended, and new claims 16-39 are submitted.

Claims 2, 3, and 5 are amended to be directed to an improved method of treating an autoimmune disease or disorder treatable by inhibiting gp39 expression or the interaction of gp39 with CD40, in compliance with the restriction requirement. Substitution of the term "inhibiting" for "modulating" gp39 expression in claim 2 is supported by the specification, *e.g.*, at page 5, lines 19-27, which describes gp39 expression by a T cell as being a prerequisite for T cell production of IFN-γ, IL-4, and IL-2; and pages 36-37, which discuss treatment of an autoimmune disease or disorder by blocking the binding activity of gp39. Claim 2 is further amended to include a step of obtaining and screening anti-gp39 antibodies to identify anti-gp39 antibodies that inhibit the gp39-CD40 interaction and are substantially non-agonistic of T-cell co-stimulation responses, as described, for example, on pages 35-37.

Claim 3 is amended to be directed to a method wherein the disease or disorder is characterized by induction of IL- 2 secretion, rather than one that is "caused by" IL- 2 secretion, in accord with the description of the invention on pages 36-37 of the invention.

Claim 5 is further amended by replacing "ITP" with the full name of the disease, for greater clarity.

New claims 16-40 are directed to various embodiments of the improved method of claim 2 that are described in the specification. New claim 16 is directed to the embodiment in which the disease or disorder is multiple sclerosis, in accord with the requirement for election of species dated January 3, 2002. The use of chimeric (*e.g.*, primatized®) or humanized anti-gp39 antibodies as directed in new claims 17-30 is described, for example, at pages 8-10 and 21-34; and screening for and using anti-gp39 antibodies that bind to the same or different epitope of gp39 as murine antibody 24-31 as directed by claims 24 and 30 is described, for

example, on page 23, and in Example 14. Screening for and administering anti-gp39 antibodies that do not induce T cells to produce cytokines or proliferate as directed in new claims 31-35 is described, for example, at pages 35-37 and in Examples 18 and 19; and a method wherein the anti-gp39 antibodies are administered parenterally at dosages as directed in new claims 36-39 is described at pages 60-61.

Patentability Remarks:

35 U.S.C. §112, Second Paragraph

Claims 2-5 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds that (i) the meaning of "modulating" in claim 2 is unclear, and (ii) the phrase "caused by IL-2 secretion" in claim 3 is not applicable to multiple sclerosis. Claims 2 and 5 are amended so that the objected-to terms are replaced by more precise terminology as discussed above. The applicants respectfully submit that the amended claims are not indefinite and request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. §102(a) and (e)

Claims 2-5 were rejected under 35 U.S.C. § 102(a)(e) as anticipated by U.S. Patent No. 6,001,358 (Black et al.), and under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,328,964 (Noelle et al.).

The Black et al. patent disclosed humanized anti-gp39 antibodies with antigen-binding portions derived from murine antibody 24-31; however, the Black et al. patent did not describe or suggest assaying anti-gp39 antibodies to determine if they are non-agonistic of T-cell co-stimulation responses such as induction of cytokine production or proliferation by T cells. In fact, until the disclosure of the claimed method in the priority application, persons of ordinary skill in the art did not know and could not have predicted that it was possible to successfully produce and select therapeutic anti-gp39 antibodies that are substantially non-agonistic of T-cell co-stimulation responses.

The Noelle et al. patent describes preparing hybridoma cells that produce murine monoclonal antibody 24-31, and it suggested making chimeric and humanized anti-gp39

antibodies derived from antibody 24-31 and administering these to treat multiple sclerosis and other autoimmune diseases. The Noelle et al. patent also did not describe or suggest assaying anti-gp39 antibodies to determine if they are non-agonistic of T-cell co-stimulation responses.

At the time the priority application was filed, one of ordinary skill in the art could not have predicted whether the anti-gp39 antibodies described by the Black et al. patent or the Noelle et al. patent were either agonistic or non-agonistic of T-cell co-stimulation responses. Furthermore, at the time the invention was made, a person of ordinary skill in the art could not have predicted that the disclosed method would operate successfully to identify therapeutic anti-gp39 antibodies that inhibit the gp39-CD40 interaction without being agonistic of T cell co-stimulation responses. Withdrawal of the rejection of the claims under 35 U.S.C. § 102(a)(e) as anticipated by U.S. Patent No. 6,001,358 (Black et al.), and under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,328,964 (Noelle et al.), is therefore respectfully requested.

Conclusion

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If any points remain in issue, which the examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,
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